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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,004	01/26/2004	Abraham H. Kryger	20308.CON	6760

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EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/765,004	KRYGER, ABRAHAM H.	
	Examiner	Art Unit	
	Barbara P. Badio, Ph.D.	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 26 January 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/6/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

First Office Action on the Merits

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/765,463. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both recite a topical testosterone formulation comprising (a) a modified poloxamer lecithin organogel carrier, (b) an arginine ingredient, (c) a tocopherol ingredient and (d) testosterone. Unlike the cited copending Application, the present claims are limited to from about 0.1 to about 20% w/w of the arginine and tocopherol ingredients. However, said amounts are recited

by claims 3 and 7 of the cited copending application and, thus, are anticipated. In addition, unlike the instant invention, the claims of the cited copending Application is limited to from about 0.5% w/w to about 25% w/w testosterone. Instant claim 2 recites said amounts of testosterone and, thus, anticipates the claims of the cited copending Application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1-20 are rejected over claims 1-22 of US Patent No. 6,743,448.

The claims are not identical but they are not patentably distinct from each other because they both recite topical compositions comprising testosterone and tocopherol. The claims of the cited patent differ from the instant claim in the recitation of (a) a method of minimizing aromatic conversion of testosterone to an estrogen and (b) the scope of the claimed composition. However, (a) the scope of the instantly claimed composition is rendered obvious by the disclosure of the cited patent (see col. 2, lines 50-61; claims 2-4, 9 and 12 of the cited patent) and (b) the method claims of the cited patent are rendered obvious by the disclosure of the instant invention since the present disclosure recites the method of the cited patent (see section 0021 of the instant disclosure).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-12, 15, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carruthers (GB 2,314,771), Reyes (US 6,803,060), Ebert et al. (US 5,152,997) and Crandall (US 6,316,428) in combination.

Carruthers discloses a topical preparation for the relief of erectile dysfunction containing aminophylline, co-dergocrine mesylate, isosorbide dinitrate and a compound, such as **L-arginine**, capable of releasing and/or carrying nitric oxide and **testosterone** (see the entire article, especially Abstract and page 3, lines 18-27).

Reyes discloses a composition for boosting the libido of an individual comprising **a compound for increasing the production of testosterone and elevating sperm production**, an aphrodisiac, a compound to increase blood flow to the pelvic area (thus causing erection), **a compound to assist in the circulation of smooth blood flow (for example, L-arginine)** and **a compound which increases sexual powers, such as vitamin E** in a pharmaceutically carrier (see the entire article, col. 6, lines 53-67; col. 7, lines 20-27).

Ebert et al. discloses a topically reservoir comprising testosterone in a carrier and a skin **permeation enhancer** for treatment of any indication for which testosterone is

indicated (see the entire article, especially col. 2, lines 53-68; col. 3, lines 23-57; col. 5, lines 4-11).

Crandall discloses **lecithin organogel** as a penetrating agent and deliver vehicle (see col. 7, lines 20-62). The reference teaches the enhancement of the diffusion of moisturizers, surfactants, etc., such as **tocopherol, arginine and steroids**, into the skin (see col. 7, line 63 – col. 8, line 37).

The instantly claimed invention is made obvious by the combined teachings of the cited prior at. The combined teachings of Carruthers, Reyes and Ebert et al. makes obvious the combination of testosterone or compounds that increase the production of testosterone, arginine and tocopherol in the treatment of testosterone related disorders including sexual dysfunction. The skilled artisan would be motivated to add lecithin organogel to said composition based on the teaching of Crandall that lecithin organogel would enhance the diffusion of molecules, including tocopherol, arginine and steroids, into the skin.

The instant claims differ by the recitation of specific amounts of arginine and tocopherol. However, the determination of amounts of the individual ingredients of a composition that would result in optimum results require only routine experimentation which is done in the pharmaceutical art and, thus, within the level of skill of the obvious artisan in the art.

Claims 10-12 and 20 further differ by the recitation of DHEA or derivatives thereof. However, DHEA and its derivatives are known precursors of testosterone (see for example, US 4,835,147, col. 1, lines 25-27; US 6,117,429, col. 1, lines 15-19) and,

thus, their use for increasing the production of testosterone and elevating sperm production as taught by Reyes would have been obvious to the skilled artisan in the art at the time of the present invention.

Based on the teachings of the cited prior art and the level of skill of the ordinary artisan in the art at the time of the present invention, the instantly claimed composition would have been prima facie obvious to one of ordinary skill in the art at the time of the present invention.

6. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carruthers (GB 2,314,771), Reyes (US 6,803,060), Ebert et al. (US 5,152,997) and Crandall (US 6,316,428) in combination, as applied to claims 1-12, 15, 16 and 19 above, and further in view of North et al. (US 5,633,276), Hadley (US 6,051,555) and Dines et al. (US 6,534,503).

The combined teachings of Carruthers, Reyes, Ebert and Crandall are discussed above in #.... The instant claims encompass the addition of other ingredients such as melatonin and oxytocin (see claims 13, 14, 17, 18 and 20). However, melatonin and oxytocin are taught in the art to be effective in sexual dysfunction, such as male erectile disorder (see for example, US 6,051,555, col. 4, lines 18-27; US 5,633,276, col. 3, lines 1-12; US 6,534,503, col. 18, lines 11-54). Therefore, the addition of melatonin and/or oxytocin in compositions useful in treating sexual dysfunction as taught by cited reference would be obvious to the skilled artisan. The motivation is based on the

knowledge in the art that both melatonin and oxytocin are useful erectogenic compounds.

Telephone Inquiry

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB
June 8, 2006